COVIDLIMS

Coronavirus (COVID-19)
SARS-CoV-2 Virus

COVID Laboratories
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PROVIDER INFORMATION		PATIENT INFORMATION		SPECIMEN INFORMATION	
Site:	Test Location	Name:	Test Patient	Lab Accession Number:	20-00001
Physician:	aaaa aaa			Specimen Type:	Nasopharyngeal
Address:			Woodstock, GA 30189	Date Collected:	9/23/2020 11:49 AM
		Phone:	866-522-5969	Date Received:	9/23/2020 11:50 AM
Phone:		DOB:	08/25/1999	Date Processed:	9/23/2020 3:04 PM
Fax:		Gender:	Female	Date Reported:	11/10/2020 3:13 PM
NPI:	12213213	MRN:	6767877		

Test Performed	Result
SARS-CoV-2 RT-PCR	**Inconclusive**

Methodogy:
Laboratory specimens associated with this report were analyzed using molecular technologies. Total nucleic acids were extracted from the submitted sample and analyzed using a combination reverse trasnscription of viral RNA and PCR amplification using real-time reverse trascriptase PCR (rRT-PCR). Internal controls run simultaneously with patienct samples ensure the correct operation of the extraction and RT-PCR steps of this assay.

Inconclusive:
An inconclusive result indicates that viral DNA was detected in the specimen, but at a concentration below the threshold required for a SARS-CoV-2 positive call. Such a result may occur due to low concentrations of SARS-CoV-2 target RNA or cross-reactivity with another strain of coronavirus.

Invalid:
An invalid result indicates that insufficient human genetic material was detected in the specimen. Such a result may occur due to improper sample collection or sample degradation due to improper transport or storage.

Disclaimer:
This test has been validated but the FDA's independent review of the validation is pending. This test is performed as a laboratory developed test; independent review of the validation under the FDA's Emergency Use Authorizaion (EUA) authority will be performed according to current guidance requirements. COVID Laboratories will continue to follow federal and state requirements for both notification of results and any confirmatory testing that is required by another agency.

This test was developed and its performance characteristics determined by COVID Laboratories, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration. Results should be used in conjunction with clinical findings, and should not form the sole basis for a diagnosis or treatment decision. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Inquiries:
Please contact COVID Labs or info@lablynx.com for assistance with this report. Please be aware that COVID LIMS cannot provide heathcare guidance directly to patients. Patients are directed to speak with their primary care physician regarding this information.

References:
https://www.cdc.gov/coronavirus/2019-ncov/index.html

This document contains private and confidential heath information protected by state and federal law. If you have received this report in error, please call (123) 456-7890

Final Report